BizInt Smart Charts

Patents Drug Pipelines Clinical Trials Sequences

"You Don't Know What You're Missing"

Evaluating Competitor Clinical Trials with the BizInt Smart Charts Product Family

November 2013 Diane Webb, President Barbara Gilmore, Application Consultant



New additions to the BizInt team







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BizInt Smart Charts takes your search results

Patents Drug Pipelines Clinical Trials Sequences

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Combining results from different databases.

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And, helps you create visualizations.





Creating a trial timeline...

Filgrastim Biosimilar (Generic) Trials 2004 2008 Abraxis BioScience - NCT00864253 Amovtop - NCT01238562 Apricus Biosciences - TrialTrovelD-136222 Bio-Ker - NCT01933971 Biocad - NCT01569087 Biocon - TrialTroveID-076807 BioGeneriX - 58322 BioGeneriX - EudraCT 2004-001449-13 BioGeneriX - EudraCT 2004-001450-84 Cadila - CRSC11002 Cephalon - NCT01177683 Dong-A - NCT00959777 Dong-A - NCT01674855 Dong-A - NCT01923545 Eurofarma - NCT01079676 Harvest Moon - Trial TrovelD-175333 Hospira - ACTRN12612000137897 Hospira - GCF071 Hospira - TrialTroveID-135758 Hospira - TrialTrovelD-136070 Insmed - TrialTrovelD-088506 Intas - TrialTroveID-087193 Intas - TrialTroveID-103617 Lupin - CTRI/2011/05/001748 Merck BioVentures - NCT00667615 Merck BioVentures - TrialTroveID-114491 S. Arzneimittel - TrialTrovelD-076036 Sandoz - NCT01519700 Sandoz - TrialTroveID-164641 Sandoz - TrialTrovelD-164688 Shandong GeneLeuk - NCT01285219 Shantha Biotechnics - NCT00776165 Teva - NCT00911183 Teva - NCT01542944 Teva - TrialTrovelD-114205 Teva - TrialTroveID-158262 Teva - TrialTroveID-158368 Zenotech - TrialTroveID-040894 Phase I Phase I Phase III Unknown start Unknown end

..to identify competitor companies working on generic filgrastim biosimilars to benchmark potential product launch timing.

bizcharts.com/slides



Task 1: Search the trial databases

 Searched two clinical trials databases: Citeline TrialTrove (TT) ClinicalTrials.gov (CT.gov)

Searched: Drug = Filgrastim

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Task 2: Import and combine search results

BizInt Smart Chartsfor Drug Pipelines3.6

- Import search results from TrialTrove and CT.gov
- **Combine** results into single report.
- Use Identify Common Trial ID tool to identify related trials across databases.
- Select the columns to display in the trial timeline (title, phase, sponsor, completion date, start date)

Task 3: Select the trial start and end dates

Filgrastim Biosimilar (Generic) Trials 2008 2009 2010 2011 2012 2013 2014 2015 Abraxis BioScience - NCT00864253 Amoytop - NCT01238562 Apricus Biosciences - TrialTrovelD-136222 Bio-Ker - NCT01933971 Biocad - NCT01569087 Biocon - TrialTrovelD-076807 BioGeneriX - 58322 BioGeneriX - EudraCT 2004-001449-13 BioGeneriX - EudraCT 2004-001450-84 Cadila - CRSC11002 Cephalon - NCT01177683 Dong-A - NCT00959777 Dong-A - NCT01674855 Dong-A - NCT01923545 Eurofarma - NCT01079676 Harvest Moon - TrialTroveID-175333 Hospira - ACTRN12612000137897 Hospira - GCF071 Hospira - TrialTroveID-135758 Hospira - TrialTroveID-136070 Insmed - TrialTroveID-088506 Intas - TrialTroveID-087193 Intas - TrialTroveID-103617 Lupin - CTRI/2011/05/001748 Merck BioVentures - NCT00667615 Merck BioVentures - TrialTroveID-114491 S. Arzneimittel - TrialTroveID-076036 Sandoz - NCT01519700 Sandoz - TrialTrovelD-164641 Sandoz - TrialTroveID-164688 Shandong GeneLeuk - NCT01285219 Shantha Biotechnics - NCT00776165 Teva - NCT00911183 Teva - NCT01542944 Teva - TrialTroveID-114205 Teva - TrialTroveID-158262 Teva - TrialTroveID-158368 Zenotech - TrialTrovelD-040894 Phase | Unknown start Unknown end

Need a trial start and end date for the timeline. Cannot always find this information in the data. And sometimes the trial is ongoing.

TrialTrove: Available Date Information

8	C:\Users\webb\AppData\Local\Temp\	Display Columns
(Citeline TrialTrove: Filgrastim	Available Columns Selected Columns
	Trial Title	Internal Comments Investigators / Contacts Last Full Review
1	Phase I bioequivalence study of IN: in healthy volunteers.	Last Modified Notes Other Drugs Start Date
2	Comparison of the Pharmacodyna Biosimilar Filgrastim and Amgen Fi from a Randomized, Phase I Trial.	Other Endpoints Patient Population Patient Segment Primary Endpoints Prior/Concurrent Therapy
3	Pharmacokinetic Profiles of a Bios And Amgen Filgrastim: Results Fro Phase I Trial	Record Number Record URL Reported Sites Study Design
ļ	A Phase I-II Study of Pentostatin, C Dituvimals and Mitovantrono in Dro	Study Keywords Supporting URLs
•	Date Ranges Search Fields	Start Date (mm/dd/yyyyy) To (mm/dd/yyyyy) End Date (mm/dd/yyyyy) To (mm/dd/yyyyy)

TrialTrove "date" information includes trial "Start Date" and "Primary Endpoints Reported" date.

CT.gov: Available Date Information

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1	Trial Title A Study Comparing Pegylated Filgrastim and Filgrastim in Support for Chemotherapy	Available Columns # Arms Acronym Arms Countries Detailed Description Eligibility Criteria Full Text Link Gender Healthy Volunteers? Interventions Maximum Age Minimum Age Num. Locations Num. Recruiting Original Title Oversight	Selected Columns Trial Title Drugs Sponsor(s) Brief Summary Overall Status Primary Outcome Secondary Outcome Enrollment Condition Start Date Completion Date Last Changed Date

CT.gov date fields include "Start Date," "Completion Date" and the "last change date" for the record.



Task 3: Select the trial start and end dates

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Reference RowsTM

- Merge data from different records for the same trial
- Use the Start Date from one record and the End Date from another.



Use the "Earliest Date" rule to select the Start Date.



Task 4: Data necessary for the timeline



- Start and end years for each trial timeline bar (2012-04-01, April 2008, 2013, 31 May 2006)
- Trial phase to color-code each trial (I, II, Phase 1, Phase 2, Phase 1/Phase 2)
- Company name and trial ID to label each trial. (e.g. Teva NCT00911183)

Extract the Year from each start/end date

Common Trial ID	~	te a					^
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	1	22	2010-03-09				
	2	22	2011-11-07			\mathbf{N}	
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	20	1 1	31 May 2006 (actual)		15	*	.5
	21	11	April 2008 (Actual)			~	
	22	111	August 2011 (Anticipated)	1	7	7 2013	
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Clean-up the Trial Phase terminology



Append the Company to the Trial ID field

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Task 5: Generate the trial timeline



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Now we can assess the trial landscape...



+ Data captures from different sources builds best picture + Identify trial milestones + Understand trial landscape before trials appear in conference papers & proceedings + Look for Phase 3 trial completion to focus your competitive intelligence searches for filing & launch information

What if we searched only TrialTrove?



* TrialTrove has broad coverage of global trial registries
* TrialTrove does not consistently provide trial end dates.
* Missed trials unique to other sources

What if we searched only CT.gov?



* ClinicalTrials.gov is a US based and produced registry, with some global information. * CT.gov filgrastim search identified 3 companies not picked up in TrialTrove.

We would miss significant trial data!







Filgrastim Biosimilar (Generic) Trials





You Don't Know What You're Missing!

- No single database provides complete trial coverage.
- Even if field exists in a given database, it is not always populated.
- Database content can overlap duplicate trial records can have different content.
- If you search multiple databases, you can capture more complete trial information.
- And you are in a better position to anticipate competitor milestones & product launches.

More sources could yield even better results

- Adis Clinical Trials Insight
- Cortellis Clinical Trials Intelligence (just announced)
- European Clinical Trials Database (EudraCT)
- And more...





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bizint.com/Cookbook